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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/578,490	05/10/2007	Muneto Mogi	BHC 03 2009	9422	
35969 7590 04/10/2009 Barbara A. Shimei EXAMINER					
Director, Patents & Licensing			KUMAR, SHAILENDRA		
	Bayer HealthCare LLC - Pharmaceuticals 555 White Plains Road, Third Floor		ART UNIT	PAPER NUMBER	
Tarrytown, NY	Tarrytown, NY 10591			1621	
			MAIL DATE	DELIVERY MODE	
			04/10/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
	10/578,490	MOGI ET AL.					
Office Action Summary	Examiner	Art Unit					
	SHAILENDRA KUMAR	1621					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence add	lress				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim 11 apply and will expire SIX (6) MONTHS from 12 cause the application to become ABANDONE	N. nely filed the mailing date of this cor D (35 U.S.C. § 133).					
Status							
1)⊠ Responsive to communication(s) filed on <u>26 Ja</u>	nuarv 2009.						
/ <u> </u>	action is non-final.						
3) Since this application is in condition for allowan		secution as to the	merits is				
closed in accordance with the practice under <i>E</i>	·						
Disposition of Claims							
4)⊠ Claim(s) <u>1-19</u> is/are pending in the application.							
4a) Of the above claim(s) <u>3.5-7 and 12-19</u> is/are	e withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6) Claim(s) <u>1,2,4 and 8-11</u> is/are rejected.	· · · · · · · · · · · · · · · · · · ·						
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/or	election requirement						
	cicolion requirement.						
Application Papers							
9)☐ The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ acce	epted or b) $\square$ objected to by the ${ t E}$	Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PT0	D <b>-</b> 152.				
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents</li> <li>2. Certified copies of the priority documents</li> </ul>	s have been received. s have been received in Applicati	on No					
3. Copies of the certified copies of the prior	•	ed in this National S	Stage				
	application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment(s)	_						
1) Notice of References Cited (PTO-892)	4) Interview Summary						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P						
Paper No(s)/Mail Date	6) Other:	.,					

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## **DETAILED ACTION**

This office action is in response to applicants' communication filed on 1/26/09.

Claims 1-19 are pending in this application. Claims 3, 5-7 and 12-19 stand withdrawn from the consideration, being drawn to the non elected invention.

Applicants' request to join the claims 3 and 5-7 in Group I, was considered but are not persuasive. In view of the prior art found while searching the species, which is closely related to the elected species, which clearly renders the instant claims unpatentable, the election requirement is given force and effect. MPEP Sec. 803.02. Accordingly, the claims have been examined solely to the extent of the elected species.

Rejection of claims 1-2, 4, and 9-11 under 35 USC 102(b) is hereby withdrawn, subsequent to applicants' arguments.

## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-2, 4 and 9-11 are again rejected under 35 U.S.C. 103(a) as being unpatentable over JP 4178362(English abstract).

Applicants argue that the reference teach 1-positional urea substituent as against 2-positional substituent claimed in herein. Applicants further allege that there is no motivation to go to 2-positional substituent from the 1-positinal in the reference. The examiner disagrees. Positional isomers are prima facie obvious as a whole absent evidence to the contrary. In re Jones 162 F. 2d 638, 74 USPQ 152; In re Mehta 146 USPQ 284; In re Kilsheimer and Haynes 146 USQ 491.

## **Double Patenting**

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-2, 4 and 8-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/575,027, or over claims 1-5, 7 of copending application No. 10/537,217. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the applications are claiming structurally similar compounds and compositions, and one of ordinary skill in the art would have obtained compounds within the generic disclosure of the above two patent applications, with the reasonable expectation of achieving a successful pharmaceutical compositions, absent evidence to the contrary.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The elected species appears to be free of prior art and is allowable.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on (571)272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SHAILENDRA - KUMAR/ Primary Examiner, Art Unit 1621

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